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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,637	03/04/2002	Milton David Goldenberg	018733-1094	8273

22428 7590 12/08/2004

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EXAMINER	
HARTLEY, MICHAEL G	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 12/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,637	GOLDENBERG, MILTON DAVID	
	Examiner	Art Unit	
	Michael G. Hartley	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *99-201* is/are pending in the application.

4a) Of the above claim(s) *99-182,194,195 and 198-201* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *183-193,196 and 197* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendments

The preliminary amendment filed11/01/2004 has been entered.

Claim Rejections - 35 USC § 103

Claims 183, 187-189, 191-193, 196 and 197 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg (USP 4,932,412) in view of Barbet (USP 5,256,395), for the reasons set forth in the office action mailed 6/1/2004.

Claim 190 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goldenberg (USP 4,932,412) in view of Barbet (USP 5,256,395), as taken above, in further view of Horowitz (USP 4,706,652), for the reasons set forth in the office action mailed 6/1/2004.

Response to Arguments

Applicant's arguments filed 11/1/2004 have been fully considered but they are not persuasive.

Applicant asserts that the examiner has not show motivation/suggestion to combine the references of Goldenberg and Barbet.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Goldenberg and Barbet are clearly in the same field of endeavor, both being drawn to method of radiotherapy or radiodiagnostic using radiolabeled antibodies, i.e., radioimmunopharmaceuticals. One skilled in the art would have been motivated to consider all of the pertinent prior art in this field when performing endeavors therein. Goldenberg discloses all of the components of the claims recited above, except for the use of the labeled

hapten/bispecific antibody system as claimed. However, Barbet specifically teaches that methods of radiodiagnosis or radiotherapy may be enhanced by the use of a labeled hapten/bispecific antibody system as claimed. Barbet teaches that the use of labeled hapten and bispecific antibody having binding sites for cancer antigen and the hapten improve the effectiveness of such radiodiagnostic/therapeutic procedures, see columns 8-9. Thus, there is clear motivation to combine the references, which is to improve the effectiveness of such radioimmuopharmaceutical methods, such as, those disclosed by Goldenberg, by using the labeled hapten/bispecific antibody system as taught by Barbet. Improved delivery and targeting is a pertinent part of such methods, and Barbet teaches on how to improve such delivery of the radiopharmaceuticals.

Applicant asserts that the office action is a classic "pick and choose" rejection.

This is not found persuasive, as such "pick and choose" usually refers to picking various components from a "laundry list" or large list of multiple possible components, with no specific teaching to pick one over the other. In the instant case, the only thing missing from Goldenberg is the use of a labeled hapten/bispecific antibody system for targeting the radioimmunopharmaceuticals. Barbet clearly teaches that such a system can improve the same type of methods disclosed by Goldenberg. This is a situation in which the art teaches the missing step of the primary reference as a clear improvement in the field of endeavor.

Applicant also asserts that there is no reasonable expectation of success.

This is not found persuasive because Barbet teaches that the methods are for improving methods of radiodiagnosis and radiotherapy. Barbet clearly teaches that the system of labeled hapten/bispecific antibody not only works, but actually is an improvement over the use of radiolabeled antibodies by themselves, as taught by Goldenberg. Obviousness does not require absolute predictability.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.

See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicant's assertion there is nothing in the references to suggest combining or that the combination would work has been discussed above. In sum, Barbet clearly teaches a way to improve the same methods of Goldenberg, by the use of a labeled hapten/bispecific antibody system over the use of a labeled antibody (as taught by Goldenberg). One skilled in the art would have considered such an improvement, as taught by Barbet, for methods in which this teaching is relevant, such as, Goldenberg, which is the type of method that Barbet is teaching such improvements. Barbet teaches that such methods work and improve radioimmunoconjugate methods.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 183-193, 196 and 197 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,387,350, for the reasons set forth in the office action mailed 6/1/2004.

Applicant request to hold this rejection is abeyance until indication of allowable subject matter is acknowledged. The rejection is maintained for reasons of record.

Conclusion

No claims are allowed at this time.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael G. Hartley
Primary Examiner
Art Unit 1616

12/6/2004